Supreme Court, U.S.
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No. 09-210

In The

Supreme Court of the United States

ROBERT E. FRAZIER,

Petitioner,

v.

KATHLEEN SEBELIUS, Secretary,
U.S. Department of Health and Human Services,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

Question #1: Did the Ninth Circuit erroneously conclude that the Rule regarding subpoenas set forth in *Richardson v. Perales*, 402 U.S. 389 (1971) applied only to Social Security claims for disability and SSI benefits and not to Social Security Medicare M+C healthcare benefits? There is a conflict among the circuits concerning the right to cross examination in any type Social Security hearing. This is an important question of federal law that should be settled by this Court.

Question #2: Where the ALJ bases the decision on law that has no application to Medicare M+C and fails to apply relevant licensing laws, can the District Court and the Ninth Circuit Court of Appeals make up for these deficiencies by applying the correct law and supply a reasoned basis for the decision which the ALJ did not give.

Question #3: Did the acts of the DHHS in failure to discipline Kaiser for violation of its contract and Medicare law, and its participation with a U.S. Attorney overtly and covertly in the defense of Kaiser's illegal acts, constitute substantial acts of encouragement, as to establish a nexus, and symbiotic relationship with a high degree of entwinement, such that DHHS became the "virtual representative" of Kaiser and Kaiser a "state actor" subject to due process?

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OPINION BELOW

The Ninth Circuit Court of Appeals did not select its Memorandum Decision for publication in the Federal Reporter, however it is reported, *Frazier v. Johnson*, 312 Fed. Appx. 879 (9th Cir. 2009) (No. 06-56652) C09.0000729<http://www.versuslaw.com>. The District Court did not publish an opinion in this case. The ALJ Decision is without citation and is reprinted in the Appendix at App. 26. The pertinent rulings are reprinted in the Appendix.

JURISDICTION

February 20, 2009 – The Memorandum Decision of the Court of Appeals for the Ninth Circuit, Case No. 06-56652 was filed and entered on the Docket.

May 07, 2009 – Order denying panel rehearing and hearing en banc filed and docketed.

July 13, 2009 – Application 09A80 for extension of time to file petition for writ of Certiorari from August 5 to October 4, 2009 submitted to Justice Kennedy.

July 22, 2009 – Application 09A80 granted by Justice Kennedy extending time to file until August 14, 2009.

The Ninth Circuit filed its decision on February 20, 2009 and entered an order denying petitioner's motion for rehearing on May 7, 2009. This Court has

jurisdiction under 28 U.S.C. § 1254(1) to review the circuit court's decision on a writ of certiorari.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Constitutional and Statutory Provisions relevant to this case are reproduced in the Appendix, and the others are cited in the body of the petition and by reference to their location in the administrative record and in the record and brief of the courts below.

STATEMENT OF THE CASE

Subject Matter JURISDICTION was exercised in the United States District Court, Central District of California under the Medicare Statute 42 U.S.C. § 1395w-22(g)(5) (C.C. Answ. Br., Add. 15), which provides for "judicial review of the Secretary's (Department of Health and Human Services) final decision under 42 U.S.C. § 405(g)." (C.C. Answ. Br., Add. 3).

In April, 2001 petitioner "Frazier," then age 74, was a Medicare M+C enrollee in a qualified Kaiser Foundation Health Plan ("Kaiser"). He was diagnosed with prostate cancer and consulted with Kaiser radiation oncology physician David C. Khan, M.D. who offered to perform radiation seed implant treatment ("brachytherapy") with "real time treatment planning." He stated that "intraoperative treatment planning"

was still "experimental" and not yet in use at Kaiser though they did have the equipment; that he had observed or participated in fifty such procedures in training and had since performed solo fifty more and that he recently had come to Kaiser to re-start the radiation seed implant program.

Frazier sought a second opinion out of network from Stephen W. Doggett, M.D. and discovered that intraoperative treatment planning used the latest technology, with "image registration" which had been in use for some time and was not "experimental."

Frazier sent a letter to Dr. Khan requesting out of plan referral to Stephen W. Doggett, M.D., a board certified credentialed radiation oncologist who had performed five hundred sixty five such procedures and was using "intraoperative treatment planning" with "image registration" for greater accuracy in the placement of the seeds, a system that already was approved by the FDA and Medicare.

The referral was denied in a letter from Dr. Khan to Frazier offering to perform a seed implant with "real time treatment planning." Dr. Doggett, who was accepted at the ALJ hearing as an expert in the field of brachytherapy (A.R. 349), did not know the meaning of this offered treatment and testified that a patient would not know this either. A blood test on 03-05-01 showed a rapid growth of cancer cells, requiring urgent treatment.

In May 2001 Frazier received curative treatment from Dr. Doggett. Kaiser denied reimbursement to Frazier.

Frazier made timely written requests to the ALJ for subpoenas and duces tecum for witnesses including Dr. Khan, Dr. Doggett, and Kaiser physician Dr. Tome, the new chief of Radiation Oncology. The requests were supported by statements of important offered relevant testimony and documents that could not be produced without subpoenas and that Dr. Khan had falsely stated that intraoperative treatment planning was "experimental." No subpoenas were issued. Dr. Doggett appeared without subpoena and testified as did Frazier. A lay consultant represented Kaiser without any medical records, and attempted to give medical hearsay testimony gleaned from her conversations with Kaiser physicians, which was stricken by the ALJ on objection that she was not a medically qualified witness.

The ALJ decision was based on all hearsay, primarily the hearsay letter to Frazier from Dr. Khan. His credibility and veracity was in issue. He was not present for cross examination. There is no evidence in the ALJ record that Dr. Khan was a board certified, credentialed specialist as required by law.

The ALJ applied the law in Title 20 CFR that had no application to Medicare M+C enrollees and it did not provide for out of plan referral and payment to the enrollee for specialty treatment where such treatment within the M+C Plan was "inadequate" to meet the needs of the enrollee.

Both the District Court and the Ninth Circuit Court of Appeals tried to make up for these

deficiencies by citing the correct Medicare M+C law and the reasoning that the ALJ did not use in arriving at his decision.

Proceedings in District Court took two years because it incorrectly was adjudicated as a trial matter rather than as a Review of an Administrative Law Judge Decision. After Frazier filed his Magistrate ordered Cross Motion for Judgment on the Pleadings the clerk noticed the parties that it was a "discovery case" for trial and reassigned the case to a different Judge but with the same Magistrate. It was Frazier's understanding that the Review would proceed by cross-motions for Judgment on the Pleadings. (D.C. Reporter Transcript #1). See statement of Genuine Issues. (D.C. Docket #38).

Frazier's Motion for Judgment on the pleadings (D.C. Docket Numbers ("D#") 4, 14, 15, 17, 18, 21), was opposed by a Motion for Summary Judgment over Frazier's objection. No defense response to The Motion for Judgment on the pleadings was ever made or docketed. The last brief, D#42, to which Frazier was not permitted a reply, was filed by the Defendant. One defense brief, D#33, lodged 05/26/2006 was not Docketed or given a number but was *placed in file – not used* on 08/23/2006. The D.C. at times treated Frazier's motion as one for Summary Judgment though no matters outside the pleadings and the A.R., which is part of the Secty's answer, were ever presented to the court. Fed. R. Civ. P. 12c. (App. 33) The use of these procedures was improper, prejudicial to Petitioner and denied due process

under the Fifth Amendment to the U.S. Constitution (App. 33), and calls for the use of this court's supervisory power to require the use of accepted and usual course of judicial proceedings.

REASONS FOR GRANTING THE PETITION

This case presents an occasion to settle issues which are of vital importance to the efficient operation of our federal courts, and responsive to the problems of millions of elderly, disabled and poor Social Security and Medicare program beneficiaries. It can change how federal court rules and procedures process appeals of ALJ Medicare M+C decisions so that they can be fairly and efficiently adjudicated without delay and with minimal burden on the beneficiary, and the courts and the government. Healthcare today is a subject of extreme current national importance and the most important on the national agenda of 300 million Americans. This case has to do with privatized healthcare, the present Medicare + Choice (renamed Medicare Advantage) has failed to achieve the above objectives and cannot be fairly administered until enrollees are entitled to constitutional protection of due process.

I. THE RIGHT TO CROSS EXAMINATION IN SOCIAL SECURITY ADMINISTRATIVE HEARINGS NEEDS CLARIFICATION BY THIS COURT. THERE IS A CONFLICT AMONG THE CIRCUITS AS TO THE RIGHT TO SUBPOENAS AND CROSS EXAMINATION AT ALJ HEARINGS AND THE APPLICATION OF *RICHARDSON V. PERALES*, 402 U.S. 389 (1971).

The Ninth Circuit concluded in its memorandum decision, that the ALJ decision was supported by substantial evidence and that the ALJ's denial of his request for subpoenas did not deny due process of law, that: "The ALJ did not abuse his discretion in denying subpoenas because there was no showing that other witnesses were necessary given the parties' submission of documentary evidence in the administrative record."

Five Circuits of the Court of Appeals have held that an absolute right to cross-examination exists in the context of a social security disability hearing: *Demenech v. Secty. DHHS*, 913 F.2d 882, 884 (11th Cir. 1990); *Lidy v. Sullivan*, 911 F.2d 1075, 1077 (5th Cir. 1990); *Coffin v. Sullivan*, 895 F.2d 1206 (8th Cir. 1990) (attorney failed to exercise right). *Townley v. Heckler*, 748 F.2d 109 (2d Cir. 1984); *Lonzollo v. Weinberger*, 534 F.2d 712 (7th Cir. 1976). An opinion from the Sixth Circuit in *Calvin v. Chater*, 73 F.3d 87 (6th Cir. 1996) is contra, citing both *Solis* and *Perales* cases, distinguishing both and denying relief because of failure to justify the request with information

required by regulations governing issuance of subpoenas.

The Ninth Circuit in *Solis v. Schweiker,* 719 F.2d 301 (1983) qualified this right where the disability applicant requested cross-examination of a crucial physician witness for bias since interrogatories were inadequate. It distinguished *Richardson v. Perales*, 402 U.S. 389, 915 S.Ct. 1420, 28 L.Ed.2d 84 (1971) where there was a failure to request cross-examination.

Senior Justice Procter HUG, Jr. was on the three judge panel that decided *Solis*, *id.*, twenty-five years ago. It is unknown whether he authored the opinion, however, the decision concluded. We therefore REVERSE and REMAND. Senior Justice HUG also was on the three judge panel that decided *Frazier v. Johnson* (App. 1) on (02/20/09) and reached an opposite conclusion in a Social Security Medicare reimbursement case. The facts were basically the same as in *Solis*. Frazier timely requested and supported requests for subpoena for cross examination of a crucial examining medical witness Dr. Khan whose opinion in a hearsay letter was the basis for denial of out of network specialty medical treatment. His credibility and veracity was questioned and cross examination was necessary since interrogatories were inadequate to test veracity and credibility as is true with bias.

Richardson v. Perales, *id.*, was a claim for disability benefits. Frazier's case is a Medicare MA

appeal for reimbursement for denied medically necessary, out of network adequate medical benefits. Both arise under the Social Security Act; *Perales* under Title II and *Frazier* under Title XVIII. Both are governed by the Administrative Procedure Act. Both by the Scope of Judicial Review of Agency action as set forth in

> **5 U.S.C. § 706 Scope of review**: "To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall – **(1)** compel agency action unlawfully withheld or unreasonably delayed; and **(2)** hold unlawful and set aside agency action, findings, and conclusions found to be – **(A)** arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; **(B)** contrary to constitutional right, power, privilege, or immunity; **(C)** in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; **(D)** without observance of procedure required by law; **(E)** unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or **(F)** unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations, the court shall review the whole

> record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error."

42 U.S.C. § 405(b)(1) provides that "Evidence may be received at any hearing before the Commissioner of Social Security even though inadmissible under rules of evidence applicable to court procedure." 5 U.S.C. § 556(d) provides: "a party is entitled . . . to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." The requirements for Subpoenas are set forth in Title 20 CFR § 404.950. (C.C. Answ. Br., Add. 24).

Both cases present questions as to what types of hearsay documents written by physicians may be received as evidence in ALJ disability and ALJ Medicare M+C enrollee reimbursement hearings despite the hearsay character of the evidence, an absence of cross-examination, and despite the presence of opposing direct expert medical testimony and in Frazier's case, the testimony of the enrollee himself that the physician made false statements to him about the medical treatment, and whether the hearsay may constitute "substantial evidence" to support an adverse decision of the ALJ.

42 U.S.C. § 1395w-22(g)(5) (C.C. Aple. Answ. Br., Add. 15) provides for appeals in Medicare M+C cases in the same manner as other Social Security hearings under 42 U.S.C. §§ 405(b) and 405(g). In

principle, the basic law and procedural rules in both proceedings are the same, however, the private interest is slightly different in the reason for the monetary benefit. *Perales* sought monetary Social Security disability insurance benefits whereas Frazier initially sought out of network healthcare, adequate treatment for cancer of the prostate and now seeks a healthcare monetary reimbursement.

In *Perales*, the court explained that the reports of the five physicians were not inconsistent and indicated no bias, and assured underlying reliability and probative value and that *Perales* had ample opportunity to exercise his right to subpoenas and cross examination but failed to do so.

The court distinguished *Goldberg v. Kelly*, 397 U.S. 254, 269, 90 S.Ct. 1011, 25 L.Ed.2d 287 (1970) as it had to do with termination of AFDC benefits and also it concerned a situation "where credibility and veracity are in issue "as they must be in many termination proceedings."

Frazier supported his request for subpoenas with proposed important facts to which the witnesses would testify and that the testimony could not be produced without subpoena. (A.R. 191-195). Interrogatories are inadequate and inappropriate to test credibility and veracity (*Goldberg v. Kelly, id.*, 269) as well as bias an issue in *Solis v. Schweiker*, 719 F.2d 301.

The risk of erroneous deprivation in a Medicare case for prostate cancer treatment is very great, since

most enrollees are elderly, and many subsist on Social Security pensions and would find it extremely difficult, if not impossible, to, obtain funds to pay for costly out of network treatment and then engage in an arduous eight year appeal seeking reimbursement. See *Uhm v. Humana Inc.*, 540 F.3d 980 Fn.16 (9th Cir. 2008). The issue of reimbursement of a monetary loss fully equates with that of *Perales* who sought a monetary disability benefit. In *Townley v. Heckler*, *id.*, at 36, 37 which involved the use of a post-hearing "vocational report," the court held that the interest of an individual in continued receipt of Social Security disability benefits is a statutorily created "property" interest protected by the Fifth Amendment, citing *Mathews v. Eldridge*, 424 U.S. 319, 332, 96 S.Ct. 893, 47 L.Ed.2d 18 (1975). Petitioner's interest is a statutorily created Medicare M+C healthcare property interest (created by the Medicare Act) by the same reasoning.

The credibility and veracity of a crucial witness, Dr. Khan, his adverse hearsay letter, and his hearsay statements as to his brachytherapy experience, has been challenged with sworn uncontroverted testimony of Frazier (A.R. 392, 393) and that of Dr. Doggett (A.R. 373) concerning the falsity of his hearsay statement that intraoperative treatment planning was "experimental."

It should be noted that Ninth Circuit Court of Appeals Senior Circuit Judge Procter HUG, Jr. who was on a three judge panel in *Frazier v. Johnson* (App. 1), also was on a three judge panel in *Solis v.*

Schweiker, *id.*, a social security disability and SSI proceeding. The ALJ decision denying benefits was reversed where requested subpoenas were denied. "*Solis*" distinguished "*Perales*" as *Perales* made no request for subpoenas.

On October 18, 2002 the enrollee made a timely written request for subpoenas for Radiation Oncologist Stephen W. Doggett, M.D. (A.R. 191-194), and for Kaiser physician David C. Khan, M.D. (A.R. 191-195). The requests explained why the subpoenas were necessary for a full presentation of the case, and facts which the witnesses and documents were expected to prove and why the facts could not be proven without subpoena and duces tecum. Interrogatories are inadequate and inappropriate to test credibility and veracity, *Goldberg v. Kelly*, *id.*, 269, as well as bias, which was an issue in *Solis v. Schweiker*, 719 F.2d 3401.

The location of the witnesses and documents were set forth in sufficient detail for them to be found. Also supplied, was a change of address for Dr. Khan and withdrawal of a request for his subpoena duces tecum (A.R. 90), and request for subpoena and duces tecum for Michael Tome, M.D., the new Chief of the Regional Oncology Center, Los Angeles. (A.R. 107). All of the above information was supplied more than five days before the hearing which was held on November 19, 2002.

The right to subpoena and cross examine a crucial witness about his hearsay medical statements

and opinion in an enrollee Medicare M+C case for denied specialty treatment for reimbursement is a Social Security case governed by *Richardson v. Perales, id.*, which needs clarification by this court.

II. AN ALJ DECISION IS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE WHERE THE RELEVANT LAW IS NOT APPLIED.

The Administrative Law Judge ("ALJ") applied incorrect law as the basis for his reasoning, findings and decision which should be set aside and declared unlawful by the reviewing courts pursuant to the Scope of Review, 5 U.S.C. § 706(2)(A) arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law, (B) contrary to constitutional right, and (E) unsupported by substantial evidence.

The ALJ in his reasoning wrongly applied Title 20 CFR § 417.440 and Title 20 CFR § 417.401 to the acts of a Medicare M+C "HMO." The ALJ reasoning for his findings and decision as set forth on page two of the decision in paragraphs five and six. (App. 3). "An enrollee of an HMO is entitled to receive from the HMO all Medicare covered services that are available to individuals residing in the HMO service area. However, the Social Security Regulations at 20 CFR 417.440 provide that a health maintenance organization (HMO) is not required to make payments to or on behalf of the enrollee for any services that are not provided directly by the HMO or under arrangements

made by the HMO unless (1) the services are emergency or urgently needed services; or (2) the services are denied by the HMO and are found on appeal to have been services that the beneficiary was entitled to have been furnished by the HMO. Emergency Services . . . are defined in . . . 20 CFR 417.401." The Administrative Law Judge concluded that "After carefully considering the entire record in this matter, the beneficiary did not have an emergent condition **or other reason** for going to an out of plan specialist."

It is clear that the ALJ did not carefully consider the entire record or he would have read Frazier's letter to Dr. Khan dated April 5, 2001. (A.R. 110-112), which explained in detail the **reasons** for going to an out of plan specialist.

The correct Medicare M+C law is found in Title 42 CFR § 422.1 (C.C. Answ. Br., Add. 25) Title 42 CFR § 422.112(a)(3) (C.C. Answ. Br., Add. 31) and Title 42 U.S.C. § 1395w-22(d)(1)(C)(D) (C.C. Answ. Br., Add. 11). Unlike Title 20 CFR (Original Medicare), Title 42 CFR § 422.112(a)(3) requires that "The MA organization arranges for **specialty care outside of the plan provider network** when network providers are unavailable or **inadequate** to meet an enrollees' medical needs. Title 42 U.S.C. § 1395w-22(d)(1)(C)(D) provides that "A Medicare + Choice organization offering a Medicare + Choice plan *may select the providers* from whom the benefits under the plan are provided [*so long as*] – (C) the plan provides for reimbursement with respect to services covered . . . and which are provided to such an individual other

than through the organization [so long as] – (D) the organization provides access to appropriate providers, including **credentialed specialists**, for medically necessary treatment and services."

The ALJ decision is not in accordance with the law and is not supported by substantial evidence where there is no evidence in the ALJ record that the physician, Dr. Khan, whose hearsay letter offered to perform radiation seed implant specialty prostate cancer treatment was a **board certified, credentialed specialist**, as required by California and federal law.

A California state statute requires that: A health care service plan . . . shall meet the following requirements: (b) Personnel employed by or under contract to the plan shall be licensed or certified by their respective board or agency, where licensure or certification is required by law. Calif. Health & Safety Code ("H&S") § 1367(b) (1978). (C.C. Reply Br., Add. 3). This is a licensing statute which is expressly excluded in the federal preemption Statute 42 U.S.C. § 1395w-26(b)(3); (C.C. Reply Br., Add. 17,17A, 17B) and 42 CFR § 422.402 (C.C. Reply Br., Add. 12).

II. (A) REVIEWING COURTS CANNOT SUPPLY CORRECT LEGAL STANDARDS AND REASONING THAT THE ALJ DID NOT CONSIDER.

Both the District Court and the Ninth Circuit Court disregarded the fact that the ALJ had not

applied the correct legal standards and attempted to make up for these deficiencies. The **District Court decision** (App. 2) on page three, last para., states: "The organization must provide access to appropriate providers and **credentialed specialists** for all necessary treatment and services. **42 U.S.C. § 1395w-22(d)(1)(D)**"; and District Court (App. 2) on page 5, para. one "there is no evidence in the record to indicate that Dr. Khan's procedure was not **medically adequate** to treat Frazier's condition. **See 42 CFR § 422.112(a)(3).**" **The Circuit Court decision** (App. 1), on page three para. one: "We conclude substantial evidence supports the administrative determination that Kaiser offered a surgical procedure ***adequate*** to treat Frazier's medical needs." "Thus, Frazier did not demonstrate that he required specialty care . . . outside of the plan or that his provider's services were unavailable or **inadequate to meet his needs 42 C.F.R. § 422.112(a)(3).**" None of these statutes or regulations were considered, cited, or relied upon in the ALJ decision. (App. 3). The **Circuit Court decision** (App. 1) on page three, 2nd para., dismissed Frazier's allegations that there was no evidence in the record that Dr. Khan was a board certified credentialed specialist, and lied to him about Dr. Doggett's treatment being "Experimental," with the statement "It is not the task of the reviewing court, however to re-weigh the evidence before the agency."

It is the duty of the Court, however, to make a de novo, thorough, in depth review of the record to see if

there is any evidence in the record on these issues. The sworn testimony of Frazier as to the false statement (A.R. 392-393) and the testimony of Dr. Doggett that the medical treatment was approved by the FDA and Medicare (not experimental) (A.R. 373) was uncontroverted.

III. THE DHHS ABUSED ITS DISCRETION BY FAILING TO DISCIPLINE KAISER, A PRIVATE ENTITY, FOR ITS VIOLATION OF MEDICARE LAW. IT ACTIVELY PARTICIPATED IN KAISER'S DEFENSE AND IS THE VIRTUAL REPRESENTATIVE OF KAISER, WHICH HAS BECOME A "STATE ACTOR" AND HAS VIOLATED FRAZIER'S FIFTH AMENDMENT RIGHT TO DUE PROCESS. THIS COURT GRANTED CERTIORARI TO ADDRESS THIS ISSUE IN *GRIJALVA V. SHALALA*, 152 F.3d 1115 (9TH CIR. 1998), WHICH WAS VACATED, AND REMANDED, BUT THE ISSUE WAS NOT DECIDED.

A California licensed Attorney and DHHS, CMS employee Gerard Keating illegally participated and assisted the U.S. Atty. in the D.C. and wrote the briefs including the brief for the Secty. Appellee in the Ninth Circuit Court (see brief cover) and conclusion page 65 signed by Atty. Gerard Keating.

The totality of the actions of Atty. Gerard Keating demonstrates that though he had no legal authority to do so, 28 U.S.C. § 516 (C.C. Reply Br., Add. 1)

United States v. Sandstrom, et al., 22 F.Supp. 190 (1938), he represented the DHHS agency and CMS in Federal Court and this conduct was the "nexus" which established a symbiotic relationship between the DHHS-CMS and Kaiser Foundation Health Plan ("Kaiser") such that the DHHS was the "virtual representative" of Kaiser.

The Secty. DHHS, and CMS have extensive statutory and regulatory powers over Kaiser and possess a number of sanctions to ensure compliance with the Medicare Statute Title 42 U.S.C. Part C § 1395w-27 (App. 34), including power to terminate the contract if Kaiser has not met its terms. The Secty. can impose various intermediate sanctions for failure to provide necessary services to an individual that are required under the law or contract, if failure has adversely affected (or has substantial likelihood of adversely affecting the individual. Sub. §§ (g)(1)(A) (App. 34) *id.*, or if it determines that Kaiser has misrepresented or falsified information that is furnished to an individual, under this part. Section (E). *Id.*

Kaiser did in this case misrepresent and falsify information about treatment of prostate cancer, that intraoperative treatment planning was "experimental" and there is uncontradicted sworn testimony of Frazier and Dr. Doggett in the A.R. to substantiate this violation. The Secty., DHHS had a duty to Sanction Kaiser for this violation of law. Instead it violated its duty and sent attorney Gerard Keating to the Federal Courts to aid and assist the United

States Attorney in Defending Kaiser, a private Corporation.

Part of the nexus which establishes a mutually dependent "symbiotic" relationship between Kaiser the DHHS and the government is the covert interaction between the Secty., CMS and Kaiser concerning settlement proceedings. The stipulation to continue a hearing date and briefing schedule (C.C. Docket #30) (D.C. Open. Br. Excerpt #8) requested by the Secty., contains the following language on page 2 lines 21-25; "In addition, the internal deliberations that the government typically engages in when considering a potential settlement are much more complicated and time consuming here because a third party Medicare plus Choice Organization, Kaiser Permanente is centrally involved in the case."

The statements of the U.S. Atty. in D.C. Transcript #1 page 4, lines 13-19 on 01/23/2006 also adds substance to the proof of covert interaction. "This is a case the likes of which I have never seen before, a Medicare part C case. It involves not only my client but a private insurer, which I believe in this case is Kaiser. It's difficult to exercise the kind of leverage we would normally like to over our client here, but we are attempting to resolve this if we can." It is quite clear that Kaiser has actively participated in this case and secretly exercised control over failed settlement negotiations. Also see argument of Atty. Keating (C.C. Answ. Br. p. 53, lines 9-11) "given the important role played by Kaiser in this matter, it was

entirely appropriate for government counsel to consult with Kaiser in representing the Secty."

Kaiser did not present even a semblance of a valid defense of its illegal actions at the ALJ hearing. No medical witnesses from the Radiation Oncology Center appeared. There was no written request for subpoena by Kaiser for Dr. Khan. Kaiser was entitled to be a party to this action in Federal Court, 42 U.S.C. § 1395w-22(g)(5) (C.C. Answ. Br., Add. 15) but did not exercise this right. It received notice of the request for judicial review and a copy of the complaint. (C.C. Reply Br., Add. 15, 15A, 15B). Kaiser relied upon the DHHS, its attorneys, and free Department of Justice attorneys to defend its illegal acts and has been unjustly enriched by many thousands of dollars in attorneys fees provided free by the government.

This is an appropriate case for the court to exercise its equitable powers to prevent unjust enrichment pursuant to Fed. R. Civ. P. Rule 71 Enforcing Relief for or Against a Non-party. "When an order grants relief for a non party or may be enforced against a nonparty, the procedure for enforcing the order is the same as for a party." (As amended Mar. 2, 1987, eff. Aug. 1 1987; Apr. 30, 2007, eff. Dec. 1, 2007) Kaiser is the non-party legally responsible for payment of the reimbursement, not the DHHS-CMS. *Irwin v. Mascott*, 370 F.3d 924 (9th Cir. 2004) supports the conclusion that the DHHS acting through its legal representatives, CMS, U.S. Attorney General and the U.S. Department of Justice is the

"virtual representative" of Kaiser. There is a close relationship between the DHHS-CMS and Kaiser. They share a commonality of relevant interest in denying reimbursement to enrollee Frazier and defending against his claim. Non-party Kaiser has had substantial participation and control of the proceedings both by defending at the ALJ hearing, declining its right to be a party, while receiving the benefit of thousands of dollars worth of free legal defense from government attorneys far exceeding the reimbursement sought, and by being the only entity legally responsible to pay reimbursement, 42 CFR §§ 422.618 (C.C. Reply Br., Add. 14) 619. (C.C. Reply Br., Add. 15). These facts are ample to establish jurisdiction and virtual representation. Finally the interests of Kaiser have been vigorously protected by the DHHS, CMS, who is the virtual representative of Kaiser through participating actions of DHHS-CMS attorneys, the U.S. Attorney General and his staff of United States Attorneys.

The above facts establish a classic relationship of "entwinement." Kaiser is also a "state actor." It failed to comply with Medicare laws about redetermination and sending records to CHDR and requiring the use of board certified, credentialed specialists for necessary brachytherapy treatment for prostate cancer and made relevant, material false statements about treatment to Frazier. This deprived him of his statutorily created healthcare property right and denied due process under the Fifth Amendment. (App. 33).

This question of whether a Health Maintenance organization ("HMO") is a "state actor" was before the Court in *Grijalva v. Shalala*, 152 F.3d 1115 (9th Cir. 1998). This Court *granted Certiorari* on May 3, 1999 – *vacated and remanded* No. 98-1284, for further consideration in light of *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 119 S.Ct. 977, 143 L.Ed.2d 130 (1999), §§ 4001 and 4002 of the Balanced Budget Act of 1997 and the Regulations of the Secty., implementing those provisions. (Procedural regulations). In *American Manufacturers v. Sullivan*, *id.*, the Respondents failed to show that they had a property interest protected by the Constitution. Frazier has shown facts that establish a property interest deprivation and that Kaiser HMO is a "state actor."

On page 24, fn3, of the C.C. Appellee Brief, Atty. Gerard Keating violated the California Rules of Professional Conduct, "Cal. Bar Rules," 5-200, "in presenting a matter to a tribunal, a member (E) shall not assert personal knowledge of the facts at issue, except when testifying as a witness. (B) shall not seek to mislead the judge or judicial officer by an artifice or false statement of fact or law." (C.C. Reply Br., Add. 7B) Rule 1-120: A member shall not knowingly assist in, solicit, or induce any violation of these rules or the State bar Act. (C.C. Reply Br., Add. 7C). Atty. Keating encouraged the judges of the Circuit Court and the District Court to violate the Code of Conduct for United States Judges "CCUSJ" and to go on a world wide web internet site to secure ex parte, extra record evidence as to the qualifications of Dr. Khan.

The C.C. Reply Br., Excerpt E9 confirms his statement that this conduct occurred also in a District Court Brief. This conduct would violate the Code of Conduct for United States Judges. Canon 3A(4) states: "a judge should neither initiate nor consider ex parte communications on the merits, or procedures affecting the merits, of a pending or impending proceeding." (C.C. Reply Br., Add. 8). These violations occurred in District Court without sanctions or opportunity to make written response or oral objection. The Court has a duty under Chapter I, Canon 3B(3), of the CCUSJ (C.C. Reply Br., Add. 8) per Administrative Responsibilities: to initiate appropriate action. (3) A judge should initiate appropriate action when the judge becomes aware of reliable evidence indicating the likelihood of unprofessional conduct by a lawyer (C.C. Reply Br., Add. 8).

The District Court, however had no difficulty in concluding that Dr. Khan was a board certified credentialed specialist as Dr. Khan referred to himself as a radiation oncologist. (App. 13-14, fn. 4). The Circuit Court Decision (App. 1) disposed of this question at App. 3, 2nd para. as to "whether Kaiser's doctors lacked proper credentials, "It is not the task of the reviewing court, however, to reweigh the evidence before the agency."

Both reviewing courts used legal standards not applied by the ALJ. Both courts attempted to make up for deficiencies in the law and facts applied by the ALJ. Reviewing courts may not supply a reasoned

basis for the agency's action that the agency itself has not given. *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Ins. Co.*, 463 U.S. 29, 103 S.Ct. 2856, L.Ed.2d 443 (1983), *SEC v. Chenery Corp.*, 332 U.S. 194, 196, 67 S.Ct. 1575, 91 L.Ed. 1995 (1947).

The ALJ did not apply the correct law to the facts. See *Townley v. Heckler*, 748 F.2d 109 (2d Cir. 1984) (reversible error). Kaiser Foundation Health Plan did not introduce any admissible evidence into the ALJ record to establish that Dr. Khan was a board certified credentialed specialist as required by law. Thus the "real time treatment planning" offered to Frazier by Dr. Khan was not "adequate" to meet the needs of the enrollee and out of network referral was required. The findings of the ALJ are not supported by the facts and the law, the decision is arbitrary, capricious, denies due process and is not supported by substantial evidence.

CONCLUSION

The Court should grant the petition for the writ of certiorari, reverse the judgment of the Ninth Circuit Court, grant Petitioner's Motion for Judgment on the pleadings, restrain the Secty., DHHS from further participation in this case and order Kaiser Foundation Health Plan, Inc. to pay reimbursement directly to Frazier pursuant to 42 CFR § 422.618, under supervision of the district court.

Respectfully submitted,

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NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

ROBERT E. FRAZIER, Plaintiff-Appellant, v. CHARLES E. JOHNSON, Acting Secretary, U.S. Department of Health and Human Services, Defendant-Appellee.	No. 06-56652 D.C. No. CV-04-01127-JVS MEMORANDUM* (Filed Feb. 20, 2009)

Appeal from the United States District Court
for the Central District of California
James V. Selna, District Judge, Presiding

Submitted October 6, 2008**

Before: HUG, SKOPIL and HALL, Circuit Judges.

Robert E. Frazier, an enrollee in a qualified Medicare plan, appeals pro se the district court's summary judgment upholding the Secretary's denial of reimbursement for the cost of surgery performed by a doctor outside of the plan. Although our review is de novo, we will not reverse the Secretary's decision

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* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

** The panel unanimously finds this case suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

unless it is "arbitrary, capricious, an abuse of discretion, not in accordance with the law, or unsupported by substantial evidence on the record taken as a whole." *Wilmot Psychiatric/Medicenter Tucson v. Shalala,* 11 F.3d 1505, 1506 (9th Cir. 1993) (internal quotation marks omitted). Applying that standard, we affirm.

DISCUSSION

Frazier contends his out-of-plan surgery was medically necessary and superior to what his plan offered. The record indicates, however, that his Medicare health provider, Kaiser Foundation Health Plan (Kaiser), offered similar, if not essentially the same, treatment that Frazier ultimately received from the out-of-plan physician. Indeed, an independent review board, the Center for Health Dispute Resolution (CHDR), rejected Frazier's request for the out-of-plan surgery, reasoning that Kaiser offered "a medically appropriate treatment plan" and there was no evidence that the out-of-plan treatment was either "medically superior" or "medically preferable" for Frazier. An administrative law judge (ALJ) also denied Frazier's request for reimbursement, finding that Frazier "did not have an emergent medical condition or other reason for going to an out-of-plan specialist" and noting that Kaiser "did not refuse medical treatment, but instead, offered [Frazier] . . . medical services that met the standard of reasonable medical care."

We conclude substantial evidence supports the administrative determination that Kaiser offered a surgical procedure adequate to meet Frazier's medical needs, such that out-of-plan specialty care was not necessary. The record indicates Kaiser's treatment was medically adequate to treat Frazier's condition and Kaiser's doctors were qualified to perform the procedure. Moreover, there is no basis to conclude that Kaiser's proposed procedure did not adequately address Frazier's concerns regarding potential side-effects. Thus, Frazier did not demonstrate that he required "specialty care . . . outside of the plan" or that his provider's services were "unavailable or inadequate" to meet his needs. 42 C.F.R. § 422.112(a)(3).

Frazier raises a litany of other arguments that are either not relevant or lack merit. He challenges, for example, the ALJ's evidentiary rulings, but an ALJ has considerable discretion in determining what evidence will be allowed. *See Atlantic-Pacific Const. Co. v. NLRB,* 52 F.3d 260, 263 (9th Cir. 1995) (noting standard of review). Frazier further contends the ALJ failed to give proper weight to whether he had special medical needs, whether Kaiser misinformed him about its procedure, and whether Kaiser's doctors lacked proper credentials and surgical experience. It is not the task of the reviewing court, however, to reweigh the evidence before the agency. *See Lockheed Shipbuilding v. Director, OWCP,* 951 F.2d 1143, 1146 (9th Cir. 1991). Finally, Frazier asserts that much of the medical evidence before the ALJ was inadmissible

hearsay. It is well settled, however, "that agencies are not bound by strict rules of evidence." *See Villegas-Valenzuela v. INS*, 103 F.3d 805, 812 (9th Cir. 1996).

Frazier also contends the district court did not adequately review the record or consider all of his issues. The district court's review of an agency decision, however, is limited in scope and employs a narrow standard of review. *Dennis v. Blount*, 497 F.2d 1305, 1309 & n.4 (9th Cir. 1974). Moreover, the court was not required to consider issues not relevant to the inquiry or go outside the administrative record. *See Loma Linda Univ. Med. Ctr. v. Leavitt*, 492 F.3d 1065, 1074 (9th Cir. 2007) (noting district court properly limited its scope of review "to what the agency actually decided").

Finally, Frazier raises various constitutional claims, but only his due process claim warrants discussion. "Due process protects against the deprivation of life, liberty, or property." *MacLean v. Dept. of Homeland Security*, 543 F.3d 1145, 1151 (9th Cir. 2008) (internal quotation omitted). Assuming the denial of Medicare benefits implicates such interests, Frazier was entitled to adequate notice and "the opportunity to be heard at a meaningful time and in a meaningful manner." *See Miranda v. City of Cornelius*, 429 F.3d 858, 866-67 (9th Cir. 2005). Although Frazier had ample opportunity to present his case, including two internal reviews by Kaiser, an independent review by CHDR, an evidentiary hearing before an ALJ, an appeal to the Medicare Appeals Council, and a hearing in federal district court, he

nonetheless argues he was denied due process in these forums because he was precluded from making "a full presentation of the case." He cites the ALJ's rejections of his requests for subpoenas, the admission of hearsay evidence, the ALJ's alleged bias, and the district court's decision to decide the matter on summary judgment.

None of these events denied Frazier due process of law. The ALJ did not abuse his discretion in denying the subpoenas because there was no showing that other witnesses were necessary given the parties' submission of documentary evidence in the administrative record. As we previously indicated, hearsay is generally admissible in administrative proceedings. Moreover, there is no indication the ALJ was biased. *See Bayliss v. Barnhart*, 427 F.3d 1211, 1215 (9th Cir. 2005) (noting presumption that an ALJ is unbiased may be overcome only by showing a "conflict of interest or some other specific reason for disqualification"). Finally, Frazier's contention that he was somehow denied due process because he filed a motion for judgment on the pleadings while the Secretary moved for summary judgment is meritless.

AFFIRMED.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. SACV 04-1127-JVS(CWx) Date August 28, 2006

Title Robert E. Frazier v. Tommy Thompson, et al.

Present: The Honorable James V. Selna

Karla J. Tunis	Not Present
Deputy Clerk	Court Reporter
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: (In Chambers) Order Granting Defendant's Motion for Summary Judgment (Fld 5-26-06) and Denying Plaintiff's Re-Noticed Motion for Judgment on the Pleadings (Fld 5-27-06)

Plaintiff Robert E. Frazier ("Frazier"), a retired attorney appearing pro se, appeals the decision of Michael O. Leavitt, Secretary of the Department of Health and Human Services ("HHS") and an Administrative Law Judge ("ALJ") upholding the denial of reimbursement by the Kaiser Foundation Health Plan ("Kaiser"). Frazier moves this Court for a judgment on the pleading while HHS seeks a grant of summary judgment in its favor. For the following

reasons, Frazier's motion is denied and HHS's motion is granted.

I. BACKGROUND

Frazier was enrolled in a qualified Medicare plus choice plan of Kaiser. (Compl., ¶ 4.) In the autum of 2000, Kaiser doctors diagnosed Frazier with a prostate cancer. (Administrate Record ["AR"] 252-53, 264-65.) Upon diagnosis, Kaiser physicians offered Frazier several treatment options: "observation alone with serial PSA and digital examination of the rectum vs surgery vs external beam radiation therapy vs prostate brachytherapy[1]. . . ." (AR 244). According to the medical report, even though Frazier was interested in permanent seed implantation, he seemed to be leaning toward observation. (AR 246.) Dr. David Khan, a Staff Radiation Oncologist with Kaiser, consulted with Frazier on March 5, 2001 (AR 230). Dr. Khan repeated the treatment options, including permanent prostate seed implantation. (AR 230).

On March 26, 2001, Frazier presented to Dr. Stephen Doggett, an out-of-plan physician. (AR 239.) On April 5, 2001, Frazier sent a letter to Dr. Khan asking for approval for an out-of-plan referral to have the procedure performed by Dr. Doggett. (AR 110-112.) In the letter, Frazier described Dr. Doggett's expertise and why he preferred the method by which

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[1] Also called seed implant therapy. (*See, e.g.*, AR 241.)

Dr. Doggett performed the brachytherapy. (AR 110-112.) Dr. Khan declined to approve the referral, noting that "this service, permanent prostate seed implantation with real-time treatment planning, is currently offered at Kaiser." (AR 230.) Kaiser formally denied the request on April 24, 2001. (AR 225-29.)

Frazier filed two internal appeals with Kaiser, which were denied. (AR 23-38, 221-23.) Frazier then appealed to an independent, outside review entity – the Center for Health Dispute Resolution ("CHDR"), which sustained the denial. (AR 113-14, 206-07.) On July 2, 2001, Kaiser requested a hearing before an ALJ. (AR 205.) Despite the denial, Frazier went ahead with the treatment by Dr. Doggett.

The ALJ held an evidentiary hearing on November 19, 2002, and upheld Kaiser's refusal to pay on January 20, 2003. (AR 335-401, 40-43.) Frazier appealed to the Appeals Counsel, which declined to review on July 27, 2004, making the ALJ's decision a final decision. (AR 1-2.) Subsequently, Frazier initiated this action.

II. STANDARD OF REVIEW

Pursuant to the Medicare statute, judicial review of the HHS Secretary's final decision is provided in accordance with 42 U.S.C. section 405(g). 42 U.S.C. § 1395w-22(g)(5). Under section 405, "the court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying,

or reversing the decision" of the Secretary. The findings of the Secretary, if supported by substantial evidence, "shall be conclusive." 42 U.S.C. § 405(g).

If substantial evidence supports the findings of the ALJ and the ALJ applied the correct legal standards, the Court will affirm the decision. *Moncada v. Chater*, 60 F.3d 521, 523 (9th Cir. 1995). The court gives deference to the Secretary's interpretations of his own regulations. *Vallejo General Hosp. V. Bowen*, 851 F.2d 229, 231 (9th Cir. 1988).

Findings of fact will be affirmed if supported by substantial evidence. *Moncada*, 60 F.3d at 523. Substantial evidence is "more than a mere scintilla but less than a preponderance – it is such relevant evidence that a reasonable mind might accept as adequate to support the conclusion." *Id.* The Court must look to the record as a whole, and to the extent that the "evidence is susceptible to more than one rational interpretation, the decision of the ALJ must be upheld." *Id.*

III. DISCUSSION

In his Motion for Judgment on the Pleadings and his Opposition to Summary Judgment, Frazier argues that the decision of the ALJ should not be affirmed because the decision was not supported by substantial evidence and because he was denied due process of law. The court will address each argument in turn.

A. Substantial Evidence Review

Frazier contends that it was medically necessary for him to use an out-of-plan doctor to treat his prostate cancer, and accordingly, the ALJ was wrong to uphold Kaiser's denial of coverage. HHS, on the other hand, contends that the evidence supports a finding that Dr. Khan's procedure was sufficiently similar to Dr. Doggett's, such that it was not necessary to use a non-Kaiser physician.

Medicare plus choice, now known as Medicare Advantage ("M+C"), provides the elderly and disabled an alternative to the traditional fee-for-service programs. 42 U.S.C. § 1395w-21-29; 42 C.F.R. 422.100. Under an M+C plan, which must be approved by HHS, the providing organization (in this case Kaiser), must provide enrollees with the basic benefits provided under the traditional fee-for-service programs. 42 U.S.C. § 1395w-22(a). The organization may also provide premium benefits. *Id.*

Generally, an enrollee in a M+C plan agrees to received covered benefits from providers selected by the M+C organization. *Id.* at 1395w-22(d)(1); 42 C.D.R. [sic] § 422.100(a). The organization must provide access to appropriate providers and credentialed specialists for all medically necessary treatment and services. 42 U.S.C. § 1395w-22(d)(1)(D). M+C also provides for reimbursement for services provided by an out-of-plan provider if, among other reasons not applicable here, the services were not emergency but were (i) medically necessary and

immediately required and (ii) it was not reasonable given the circumstances to obtain the services through the organization. *Id.* at § 1395w-22(d)(1)(C)(i). Medicare regulations further provide that an M+C organization must also reimburse for (1) ambulance services; (2) emergency and urgently needed services; (3) maintenance and post-stabilization care services; (4) renal dialysis while enrollee outside of service area; (5) and services initially denied but found coverable on appeal. 42 C.F.R. § 422.100. Moreover, an M+C organization must provide for "necessary specialty care . . . outside of the plan network when network providers are unavailable or inadequate to meet an enrollee's medical needs." *Id.* § 422.112(a)(3). In such circumstances, the out-of-plan provider must accept as payment in full, the amount that the provider would collect if the enrollee were a Medicare beneficiary not enrolled under an M+C plan. 42 U.S.C. § 1395w-22(k)(1).

Here it is undisputed that Frazier went to an out-of-network physician, Dr. Doggett, for his prostate cancer treatment. The only question presented is whether Dr. Khan's procedure was adequate to meet Frazier's medical needs, such that out-of-plan specialty care was not necessary.

The ALJ determined that Kaiser's denial was appropriate and that Medicare through Kaiser, was not required to cover the cost of the medical care received outside the plan. (AR 32.) In so deciding, the ALJ relied on, "all the evidence in the record," including Dr. Khan's letter, Kaiser's letter upholding its

denial of referral, and Dr. Doggett's testimony. (AR 31.) The ALJ decided that Kaiser's treatment included permanent seed implantation with real time planning and that although it used a different isotope and delivery system, the potential for cure was the same as that used by Dr. Doggett. (AR 31-32.) The ALJ concluded that Frazier did not have an emergent medical condition or other reason for going to an out-of-plan specialist. (AR 31-32.)

Having reviewed the record in depth, the Court finds that the ALJ's decision is supported by substantial evidence. First, as the ALJ noted, the cure rate for external beam radiation, seed implant, and surgery are the same at the five year point, with the seed implant having the lowest complication rate. (AR 356-57.) Moreover, according to Dr. Doggett, the chance for cure with either seed type is identical. (AR 364.) Though there are differences in terms of the procedure actually used,[2] as the ALJ noted, Dr. Khan

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[2] There are apparently a wide variety of seed implantation methods. Dr. Doggett explained that with the old preplanning method, whereby an ultrasound is taken two weeks in advance, which serves as the basis for the treatment plan. (AR 368.) According to Dr. Doggett, over time, practitioners recognized that because there are differences in the tension of the prostate when the patient is awake for the ultrasound versus asleep for the procedure, this method had serious disadvantages. (AR 368) A second method, Dr. Doggett's approach, uses an intraoperative treatment planning image registration, which allows for the creation of the treatment plan in the operating room and includes the use of optical sensors that in real time tells the computer where the probe is and compensates for motions of the

(Continued on following page)

informed Frazier that he was capable of performing "permanent prostate seed implantation with real-time treatment planning." (AR 230) Although Dr. Doggett did not know what this phrase meant, there is no evidence in the record to indicate that Dr. Khan's procedure was not medically adequate to treat Frazier's condition. *See* 42 C.F.R. § 422.112(a)(3).[3] Additionally, there is no evidence in the record that indicates that Dr. Khan was not capable of performing the procedure.[4] Moreover, as noted by the

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probe and the prostate during surgery. (AR 369-70.) Dr. Doggett conceded that there are only about forty units that do image registration and that is not highly used in the local community. (AR 371, 386.) Also included in the administrative record is an article entitled "Intraoperative Planning and Evaluation of Permanent Prostate Brachytherapy: Report of the American Brachytherapy Society," written by, among others, Dr. Doggett. This article described various methods of intraoperative treatment, including the intraoperative planning system engaged by Dr. Doggett (AR 156-64.) One method described in the article and alluded to by Dr. Doggett is called intraoperative preplanning, whereby the ultrasound is performed in the operating room and images are imported in real time into the treatment planning system. (AR 157.) Intraoperative preplanning does not account for intraoperative changes in the prostate. (AR 158.)

[3] Dr. Doggett did find, in his practice, fewer complications with use of Palladium seeds. (AR 365.)

[4] Frazier argues that Dr. Khan was not a board certified radiation oncologist and was too inexperienced to perform that procedure. Although the issue of certification was not presented to the ALJ, the Court notes that in the letter of denial to Frazier, Dr. Khan is listed as a "Radiation Oncologist" and in the medical reports issued by Dr. Khan were entitled "Radiation Oncology Consult Report." (AR 244-46, 230.) Moreover, Frazier

(Continued on following page)

ALJ, Frazier's condition was not an emergency as he waited over seven months to have the procedure performed. (AR 31.)[5]

Finally, the medical journal articles provided do not support Frazier's contention that Dr. Doggett's procedure was necessarily more appropriate to treat his condition. First, medical research has not yet determined that Palladium is more effective that Iodine. (AR 327, 101.) In fact, according to one journal, use of Iodine is more common in treating cancers that are slow-growing, such as that experienced by Frazier and has "greater cell-kill" as compared with Palladium. (AR 98, 102, 230.) Moreover, the articles presented seem to indicate that there are many methods of intraoperative delivery systems, beyond the ones described by Dr. Doggett. (AR 156-64.) Although at one point in the hearing, the ALJ characterized Kaiser's method as preplanning,

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offers no evidence that Dr. Khan was not a radiation oncologist. With respect to the issue of Dr. Khan's experience, based on evidence submitted by Frazier, Dr. Khan had performed over fifty procedures and had participated or observed fifty more, which according to the Dr. Doggett was sufficient experience. (AR 231, 360-62.)

[5] Furthermore, the "urgently needed services" exception did not apply as Frazier was not out of Kaiser's service area and Kaiser's physicians were not unavailable. 42 U.S.C. 1395w-22(d)(1)(C). The exception for coverage of services that were denied but that the enrollee was entitled to similarly does not apply. *See* 42 C.F.R. § 422.100(b)(1)(v).

Kaiser's representative, Janice Block,[6] described the system as both involving a preplanning stage and an intraoperative ultrasound to enable real time adjustments. (AR 387.)

At oral argument, Frazier expressed that his concern regarding sexual side-effects was a primary consideration in choosing Dr. Doggett's method over that provided by Kaiser. The government conceded that the incidence of sexual side effects was a valid consideration in determining whether Kaiser's procedure reasonably met Frazier's needs. Both Frazier and the government conceded at oral argument that Kaiser provided the four basic treatment approaches (observation, surgery, external beam radiation, and brachytherapy) and that according to the information provided in the record, seed implantation brachytherapy in general resulted in the fewest sexual side effects (AR 180, 347). The parties disputed, however, whether the testimony of Dr. Doggett established that his method provided for less sexual side-effects than the treatment offered by Dr. Khan. Although Dr.

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[6] Although many of Janice Block's statements were in fact hearsay and not considered by the ALJ, the statement about the procedure was made in response to the ALJ's suggesting that Kaiser's method was preplanning. The ALJ noted that it was hearsay and stated that he would consider that fact when reviewing the evidence. HHS, however, is not restricted by the rules of evidence and thus the ALJ was entitled to rely on hearsay evidence. 42 U.S.C. § 405(b)(1); *see also Villegas-Valenzuela v. INS*, 103 F.3d 805, 812 (9th Cir. 1996) (noting that it is a "well-settled rule that agencies are not bound by the strict rules of evidence").

Doggett did testify that a procedure conducted by an inexperienced surgeon could result in injury to the surrounding tissue (AR 372), that his own experience tends to show that patients who had the Palladium seeds tended to be more comfortable (AR 365), and that radiation coverage is better if intraoperative treatment is used as opposed to preplanning (AR 375, 379-40), Dr. Doggett never stated that the sexual side-effects resulting from his treatment differed from that of Dr. Khan. Rather, Dr. Doggett merely testified that he was unsure what type of procedure Dr. Khan was describing in his denial letter to Frazier. (AR 383.) Moreover, the Court re-reviewed the scientific journal articles presented in the administrative record and found no evidence differentiating the Burdette system from other seed-implantation therapies in terms of sexual side effects. There is no basis in the record to conclude that the seed implantation procedure offered by Dr. Khan did not reasonably address Frazier's concerns about sexual side-effects.

The Court finds that these factors sufficient evidence to support the ALJ's finding that Kaiser's method included "permanent seed implantation with real time treatment planning" that had the same potential for cure as Dr. Doggett's method. (AR 31-32.) As the ALJ noted, Kaiser did not deny medical care, but rather offered an in-plan option that met the standard of reasonable medical care. (AR 32.) Although Frazier may disagree with that finding, a difference in opinion is not enough for this Court for

overrule an ALJ finding. *Moncada*, 60 F.3d at 523. Accordingly, the decision of the ALJ is affirmed.

B. Due Process

Frazier also contends that he was denied due process of the law when he was "deprived of the property interest of reasonable, necessary, competent and curative treatment for diagnosed prostate cancer," for which he paid a monthly premium. (Pl. Opp'n, p. 26.) In so contending, Frazier argues that: (I) HHS cannot delegate decision-making responsibility to Kaiser; (2) not all documents were given to the CHDR, the independent reviewing agency that reviewed Kaiser's denial; (3) the HHS General Counsel should not be representing HHS in this matter; (4) the ALJ was biased, restricted Frazier's right to a hearing, and wrongly denied his request for subpoeanas [sic]; and (5) that he was denied substantive due process and equal protection of the law. The Court will address each argument in turn.

1. Delegation of Decision-Making Authority to Kaiser

First, Frazier contends that it was improper to delegate decision-making responsibility to Kaiser. (Pl. Mot'n, p. 10.) However, pursuant to the Medicare Statute, a M+C organization is required to have a procedure for making determinations regarding whether an enrollee is entitled to a health care service. 42 U.S.C. § 1395w-22(g)(1)(A). Accordingly, it

was not improper for Kaiser to conduct the first level of review of Frazier's request for coverage.

2. Review by the CDHR [sic]

Next, Frazier asserts that the all relevant information was not provided to CHDR and that therefore its decision was not based on a review of all the evidence. (Pl. Mot'n, p. 10.) According to Frazier, it was improper for the ALJ to rely on CHDR's decision. (*Id.*) Having reviewed the ALJ's decision, the Court notes that the ALJ did not in fact rely on the decision of the CHDR, but rather mentioned the decision as a part of the procedural history of the case. (AR 31.) Accordingly, even if CHDR's decision was based on incomplete information, it did not form the basis of the ALJ's decision.

3. Role of the HHS General Counsel

Third, Frazier contends that the HHS general counsel was improperly involved in writing HHS's moving papers and appearing at the settlement conference. First, the Court notes that all of HHS' moving papers were signed by Russell Chittenden, an Assistant United States Attorney. Moreover, while it is true that once an agency has handed a case to the Department of Justice, that agency ceases to have control of the case, *Village of Kaktovik v. Watt*, 689 F.2d 222, 234 (D.C. Cir. 1982), Frazier cites no support for the argument that the agency is not permitted to support the Justice Department throughout the

litigation. The Court finds no problem with HHS's involvement and finds that Frazier suffered no harm as a result.

4. Problems Associated With the Hearing

Frazier further contends that the ALJ was biased and did not permit him access to a full and fair hearing. Frazier is correct that due process requires impartiality on the part of the hearing officer or ALJ. *See Shweiker v. McClure*, 456 U.S. 188, 195 (1982). The Court, however, must start from the presumption that the ALJ is unbiased. *Id.* Frazier can rebut this presumption by "showing . . . a conflict of interest or some other specific reason for disqualification." *Id.* at 195-96. To support this assertion, Frazier argues that the ALJ improperly (1) limited which issues were to be addressed; (2) suggested to Frazier that he rest his case after Dr. Doggett finished testifying and did not allow Frazier to testify; and (3) allowed Janice Block to testify regardless of her hearsay statements.

Taking first the matter of deciding which issues were to be addressed at the hearing, the Court notes that the Medicare Statute and accompanying regulations provide that the issues in a hearing are determined by the specific issue under appeal. 42 U.S.C. § 405(b); 20 CF.R. § 404.929. Though an ALJ may consider a new issue, the regulation couches this in permissive language and does not require the ALJ to consider new issues. 20 C.F.R. § 404.946. Second, the Court notes that although the ALJ did suggest to

Frazier to rest after Dr. Doggett finished testifying, this was because, according to the ALJ, Dr. Doggett's testimony was sufficiently thorough. (AR 386). Moreover, Frazier was given the opportunity to testify and give a closing argument. (AR 390-94.) Finally, as discussed above, the ALJ did strike Janice Block's testimony, even though he was not required to do. "Bias cannot be inferred from a mere pattern of rulings by a judicial officer, but requires evidence that the officer had it 'in' for the party for reasons unrelated to the officer's view of the law." *McLaughlin v. Union Oil Co. of Cal.*, 869 F.2d 1039, 1047 (7th Cir. 1989). The Court finds that Frazier's complaints about the hearing do not meet this standard.

Frazier also contends that the ALJ acted improperly in denying his request to subpoena the testimony of five individuals. The Medicare Statute and regulations authorize the issuance of subpoenas but leave it to the discretion of the ALJ. 42 U.S.C. § 405(d); 20 C.F.R. § 404.950(d)(1). The Ninth Circuit has held that the ALJ has discretion to decide when cross-examination is warranted, such that a subpoenas should be issued. *See Copeland v. Bowen*, 861 F.2d 536, 539 (9th Cir. 1988) (citation omitted). An ALJ may only issue the subpoena when it is reasonably necessary for the full presentation of a case. 20 C.F.R. § 404.950(d)(1). Frazier requested a subpoena for the following five individuals: (1) Dr. Cliff Burdette; (2) Dr. Doggett; (3) George Halvorson; (4) Dr. Michael Tome; and (5) Dr. Khan.

1. *Dr. Cliff Burdette*: Dr. Burdette invented the brachytherapy system and Frazier sought his testimony regarding that invention. (AR 196). Given the numerous medical and scientific journal articles in the record describing the Burdette system, the Court does not find that Dr. Burdette's testimony was reasonably necessary to for the full presentation of a case. Accordingly, the ALJ did not abuse his discretion in denying the request to subpoena Dr. Burdette.

2. *Dr. Doggett*: As above, the Court does not find that a subpoena of Dr. Doggett was reasonably necessary for the full presentation of the case. The record is replete with evidence of Dr. Doggett's credentials, including his own articles on brachytherapy. (AR 239-42, 268-88.) Moreover, Dr. Doggett did appear to testify, and therefore any failure to issue the subpoena was harmless.

3. *George Halvorson*: Mr. Halvorson is Kaiser's chief executive officer. There is no evidence in the record that Mr. Halvorson had any knowledge about Frazier's condition or case, or any information about treatment options provided by Kaiser or Dr. Doggett. Frazier sought Mr. Halvorson's testimony on issues such as compensation of physicians and referral policies. (AR 197-98.) However, there are documents in the records that provide this information. (AR 153-55, 199-200.) Accordingly, the Court does not find that Mr. Halvorson's testimony was reasonably necessary for the full presentation of the case.

4. *Dr. Michael Tome*: Frazier sought documents from Dr. Tome after he discovered that Dr. Khan was no longer associated with Kaiser, and he sought the testimony of Dr. Tome regarding Kaiser's policy on the use of brachytherapy. (AR 107.) Although Dr. Tome may have had access to the documents sought, there is no evidence that Dr. Tome, a pediatric radiation oncologist (*see* AR 230), would have had knowledge about Kaiser policies at that time relating to brachytherapy. Without this offer of proof, the Court cannot say that the ALJ abused his discretion.

5. *Dr. Khan*: Having reviewed the record, the Court finds that although Dr. Khan's may have been helpful during the hearing, his testimony was not reasonably necessary for the full presentation of the case. First, the Court notes that Frazier testified as to what treatment options Dr. Khan had offered to him. (AR 391-94.) Moreover, Dr. Khan's medical reports are a part of the administrative record. (AR 245-246.) The record also contains Dr. Khan's denial letter, in which he explains that he is able to perform "permanent prostate seed implantation with real-time treatment planning." (AR 230.) On this basis, the Court finds that the ALJ did not abuse his discretion in denying the request to issue the subpoena.

5. Equal Protection and Due Process

Frazier's final argument is that was generally denied equal protection and due process of the law. In so arguing, Frazier adopts the reasoning set forth in

Grijalva v. Shalala, 152 F.3d 1115 (9th Cir. 1998), *vacated*, 526 U.S. 1096 (1999). Essentially, Frazier seems to be asserting that he was denied procedural protections and deprived substantive due process under the Fifth Amendment, and was discriminated against on the basis of his economic status in violation of the Fourteenth Amendment. With respect to the due process argument, as the Court explained above, the ALJ determined that Dr. Khan's procedure was medically adequate and that Kaiser/Medicare was not required to pay for an equally effective though slightly variant procedure. Accordingly, to the extent that Frazier contrated [sic] with Medicare and Kaiser for the provision of medical benefits and to the extent that Dr. Khan's procedure was medically adequate, Frazier was not denied a benefit for which he contracted. Rather, he was denied a benefit that fell outside the terms of Medicare Statute. On this basis, the Court cannot say that Frazier was denied a property interested [sic] requiring procedural, protections[7] nor was he deprived of a liberty interest protected under the concept of substantive due process.

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[7] The Court notes, however, that Frazier was given notice of the denial, had many opportunities to appeal the denial, and had a full and fair hearing before an ALJ. *See Lachance v. Erickson*, 522 U.S. 262, 266 (1998) (noting that the core of due process includes the right to notice and an opportunity to be heard.)

Similarly, the Court does not find that Frazier has established a violation of the Equal Protection Clause. Frazier contends that unlike the Social Security Act, which provides protections against overcharging attorneys, the Medicare Statute provides no such protection. Accordingly because he does not have the financial wherewithal to hire counsel, he has suffered discrimination (Pl. Opp'n. pp. 30-31.) The Supreme Court has never held that wealth alone provides an adequate basis for employing a strict scrutiny analysis and striking a statute, but where there is also the denial of a fundamental right, such an analysis may be employed. *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 29 (1973). As explained above, Frazier has not established that he has been deprived of a fundamental right. Accordingly, the actions will be upheld if there is a rational relationship between the disparte treatment and a legitimate governmental purpose. *Cent. St. Univ. v. Am. Ass'n of Univ. Professors*, 526 U.S. 124, 127-28 (1999). In the instant case, however, Frazier's charge fails because the statute and regulations that regulate attorneys fees for Social Security disability cases are incorporated by the Medicare Statute and implementing regulations. 42 U.S.C. § 1395ii ("The provisions of section [ ] 406[8] . . . of this title . . . shall also apply with respect to this subchapter to the same extent as they are applicable with respect to

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[8] 42 U.S.C. section 406 is the provision of the Social Security Act that regulates attorneys.

subchapter II [social security benefits subchapter]. . . .”). Accordingly, the attorney regulating provisions apply equally to social security disability and medicare benefits cases, and therefore comply with the Equal Protection clause.

IV. CONCLUSION

For the foregoing reasons, Frazier's motion is denied and HHS's motion is granted.

Counsel for defendant shall prepare, serve and lodge, forthwith, a proposed judgment consistent with the Court's ruling.

_____ : _____

Initials of Preparer /s/ [Illegible]

SOCIAL SECURITY ADMINISTRATION
Office of Hearings and Appeals

DECISION

IN THE CASE OF	**CLAIM FOR**
Robert Frazier (Appellant)	Medicare + Choice Benefits (Part C)
(Beneficiary)	[Social Security Number Omitted] (HICN)
The Center for Health Dispute Resolution (Carrier/Intermediary/ PRO	(Docket Number)

This case is before the Administrative Law Judge pursuant to a request for hearing filed on July 2, 2001. After proper notice, a hearing was held in Orange, California on November 19, 1992 [sic]. The appellant/beneficiary, who appeared and testified at the hearing, made a knowledgeable and voluntary waiver of the right to legal representation. Janice Bock was present as a representative of the Health maintenance organization. Stephen W. Doggett, M.D. also testified as a witness on behalf of the appellant.

ISSUE

The general issue is whether Kaiser Foundation Health Plan is financially responsible for the services rendered to the beneficiary by non-contract providers

under Section 1852(d) of Title XVIII of the Social Security Act.

EVALUATION OF THE EVIDENCE

The beneficiary, Robert Frazier, was enrolled in Kaiser Foundation Health Plan, a federally qualified Medicare + Choice Organization (M + CO). There is no allegation that the beneficiary did not understand the terms of the enrollment contract.

The evidence shows that during the period in question the beneficiary was a 74 year old man who was diagnosed with adenocarcinorna of the prostate (Ex 2 pg 8). According to the medical records, in February 2001 and March 2001, the beneficiary sought opinions from Aroor Rao, M.D., and David C. Khan, M.D, both plan physicians, who discussed treatment options with the claimant of prostate brachytherapy, external beam radiation therapy, or observation along with serial PSA and digital examination (Ex 2 pgs 8 & 9). Thereafter, on March 26, 2001 he sought an additional opinion from Stephen W. Doggett, M.D., a non-plan radiation oncologist, who essentially offered the same options as previous physicians, i.e., watchful waiting, hormone therapy, external beam radiotherapy, seed implant, radical prostatectomy or combination of the above.

In response to the beneficiary's request for a referral to Dr. Doggett, on April 10, 2001, Dr. Khan advised

the beneficiary that permanent prostate seed implantation with real-time treatment planning was offered at Kaiser, and that he did not feel it either appropriate or necessary for referral to an outside facility, but that he would provide permanent seed implantation, external beam radiation therapy or continued expectant management if the beneficiary so desired (Ex 4).

On April 24, 2001, the HMO issued an initial determination denying the beneficiary's request for referral to Dr. Doggett for brachytherapy (Ex 5 pg 1). The beneficiary was advised that if he received the service he would be financially responsible. On May 8, 2001 the beneficiary appealed the decision denying referral. In their expedited review determination on May 10, 2001, the HMO upheld their original denial, noting that seed implantation using Iodine-124 incorporating real-time planning was available through the plan (Ex 7F pg 8). On May 25, 2001 the Center for Health Dispute Resolution issued a reconsideration determination, finding that the HMO was not financially responsible for coverage as the HMO had offered the beneficiary a medically appropriate treatment plan.

At the hearing, Dr. Doggett testified that he treated the claimant for prostate cancer with Palladium seed implantation utilizing the Burdett system with intra-operative planning image registration. He testified that surgical removal of the prostate, use of external beam radiation or proton therapy, or the use of radiation seed implants were considered to have the

same cure rate, but that seed implant offered the lowest rate of complications such as urinary leakage and impotency. Dr. Doggett testified that the chance for cure from either radioactive iodine or Palladium seeds were identical, but that there were less complications from the Palladium variety. He indicated that the image registered treatment planning system was not highly used in the local community, but that there were several hundred alternate systems in use throughout the United States.

An enrollee of an HMO is entitled to receive from the HMO all Medicare covered services that area available to individuals residing in the HMO service area. However, the Social Security Regulations at 20 CFR 417.440 provide that a health maintenance organization (HMO) is not required to make payments to or an behalf of the enrollee for any services that are not provided directly by the HMO or under arrangements made by the HMO unless (1) the service are emergency or urgently needed services; or (2) the services are denied by the HMO and are found on appeal to have been services that the beneficiary was entitled to have been furnished by the HMO. Emergency services are defined in the Medicare regulations as services that are needed immediately because of an injury or sudden illness, and are such that the time required to reach the HMO's providers would mean risk of permanent damage to the enrollee's health (20 CFR 417.401).

After carefully considering the entire record in this matter, the Administrative Law Judge concludes that

the beneficiary did not have an emergent medical condition or other reason for going to an out-of-plan specialist. The record reveals that the beneficiary consulted with Dr. Rao and Dr. Khan, both of whom were plan providers, and who offered the claimant treatment for his prostate cancer, which included permanent seed implantation with real time treatment planning. Dr. Doggett offered the same treatment, i.e., seed implantation, albeit with a different isotope and delivery system. It was acknowledged at the hearing that the potential for cure utilizing either Palladium or radioactive iodine seeds were the same, and that several hundred alternate delivery systems other than the Burdette implant system were in use across the United States. The HMO did not refuse medical treatment, but instead, offered the beneficiary with medical services that met the standard of reasonable medical care.

Moreover, the beneficiary did not present with an emergency as defined in the Regulations. It is apparent from the record that there were several months between the elapsed time of the beneficiary's diagnosis of prostate cancer before his initial visit with Dr. Doggett.

Therefore, the Administrative Law Judge finds that Medicare, under Kaiser Foundation Health Plan, is not required to cover the cost of medical care received outside the plan of Palladium 103 Burdett [sic] Interplant Brachytherapy.

FINDINGS

After consideration of the entire record, the Administrative Law Judge makes the following findings:

1. The beneficiary was enrolled in the Kaiser Foundation Health Plan, a Medicare + Choice organization.

2. Medically appropriate treatment which met the standard of reasonable medical care was available through Kaiser Foundation Health Plan.

3. Medicare, through Kaiser Foundation Health Plan, is not financially responsible for coverage of treatment rendered by the out-of-plan provider for Palladium 103 Burdett Interplant Brachytherapy.

DECISION

It is the decision of the Administrative Law Judge that Medicare payment to or on behalf of the beneficiary, Robert Frazier, is not required by Kaiser Foundation Health Plan for the services rendered by an out-of-plan provider for Palladium 103 Burdett Interplant Brachytherapy.

/s/ Milan M. Dostal
Milan M. Dostal
Administrative Law Judge

Jan. 30, 2003
Date [/s/ KG]

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ROBERT E. FRAZIER, Plaintiff-Appellant, v. MICHAEL LEAVITT, Defendant-Appellee.	No. 06-56652 D.C. No. CV-04-01127-JVS Central District of California, Santa Ana ORDER (Filed May 7, 2009)

Before: HUG, SKOPIL and HALL, Circuit Judges.

The panel has voted unanimously to deny the petition for rehearing. The full court has been advised of the petition for rehearing en banc and no active judge has requested a vote on whether to rehear the matter en banc. *See* Fed. R. App. P. 35. Accordingly, the petition for rehearing is DENIED and the petition for rehearing en banc is DENIED.

U.S. Constitution: Fifth Amendment

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or pub'c danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

Federal Rules of Civil Procedure – Rule 12 (LII 2007 ed.)

(c) Motion for Judgment on the Pleadings.

After the pleadings are closed – but early enough not to delay trial – a party may move for judgment on the pleadings.

(d) Result of Presenting Matters Outside the Pleadings.

If, on a motion under Rule 12(b) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment *under Rules 56*. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.

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42 U.S.C. § 1395w-27(c)(2)

Contracts with Medicare + Choice Organizations : Termination authority. In accordance with procedures established under subsection (h) of this section, the Secretary may at any time terminate any such contract if the Secretary determines that the organization (A) has failed to substantially carry out the contract; (B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or (C) no longer substantially meets the applicable conditions of this part. (g) Intermediate Sanctions (1) In General, if the Secretary determines that a Medicare + Choice organization with a contract under this section – (A) fails substantially to provide medically necessary items and services that are required (under the law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual; (E) misrepresents or falsifies information that is furnished (i) to the Secretary under this part, or (ii) to an individual or any other entity under this part; the Secretary may provide in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2). Remedies. The remedies described in this paragraph are – (A) Civil money penalties of not more than $25,000 for each determination under paragraph (1) . . . (B) suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination

under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, etc.